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EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/802,273	RODRIGUEZ, GUSTAVO C.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-19 are presented for examination.

Applicant's Amendment filed September 6, 2005 has been received and entered into the application. Accordingly, the specification at pages 1, 10-12, 16, 21, 46, 48-49, 63 and 74 has been amended, claim 1 has been amended and claims 2-19 are newly added.

In view of the amendments and accompanying remarks, the objections to claim 1 and the objections to the specification have each been hereby **withdrawn**.

Claim Rejection - 35 USC § 112, First Paragraph, Written Description (New Ground of Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 4-6 and 15-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims have been amended by the amendment filed September 6, 2005, to contain particular dosage amounts and multi-phasic administration that are not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor, at the time the application was filed, had possession of the claimed invention. "If new matter is added to the claims, the Examiner should reject the claims under 35 U.S.C. 112, first paragraph-written description requirement. *In re Rasmussen.* 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." (See MPEP §2163.06(I)).

In particular, the specification as originally filed fails to provide support for an amount of

norgestimate in the range of 0.5-0.8 mg (see present claim 2); norgestimate in the range of 0.8-1.2 mg (see present claim 4); norgestimate in a daily dose of 1.0 mg (see present claim 5); norgestimate in the range of 1.0-1.8 mg (see present claim 6); multi-phasic regimen with one phase having a daily dosage of norgestimate of at least 0.5 mg and another phase having daily dosage of norgestimate of less than 0.25 mg (see present claim 15); multi-phasic regimen with one phase having a daily dosage of norgestimate of at least 0.8 mg and another phase having a daily dosage of norgestimate of less than 0.25 mg (see present claim 16); or wherein the regimen consists of 21-28 daily dosages for a cycle (see present claims 17-19).

Respecting the claimed dosage amounts and regimens, Applicant is advised that the issue is not whether the presently claimed dosage ranges or periods of administration falls within the open-ended ranges disclosed in the specification as originally filed (i.e., "at least 0.5 mg of norgestimate, preferably at least 0.8...", see last paragraph at page 35 of the specification, for example, where the present claims now recite norgestimate in a range of 0.5-0.8 mg), but rather whether the concept of such a range was present in the specification as originally filed.

In the absence of any direction by Applicant as to where support for such ranges may be found in the disclosure as originally filed, the claims as previously filed, as well as the specification as a whole, have been carefully reviewed, but adequate support for the subject matter that is now claimed cannot be located.

In particular, the specification as originally filed contains the following disclosure concerning the dosage amounts of norgestimate to be administered in combination with ethinyl estradiol and the time period over which administration is intended to occur:

"This invention contemplates mono-phasic or multi-phasic OCP regimens for reducing the risk of ovarian cancer by regulating TGF-beta expression and/or increasing apoptosis and/or altering expression of surrogate biomarkers ovarian epithelium cancer protection in the ovarian epithelium where the regimens have at least one or more of the daily dosages having at least 0.5 mg of norgestimate, preferably at least 0.8, more preferably at least 1.2, and even more preferably at least 1.8, and most preferably at least 2.5 or more. In multi-phasic, this phase of the regimen is administered at least one day, more preferable at least two days or alternatively at least 3 days. Preferred ranges for the length of this phase in multi-phasic regimens are from 1-15 days, from 2-11 days, and from 3-7 days. The estrogen level used in this regimen preferably has no daily dosage exceeding 50 mcg EE dosage equivalent, and more preferably not to exceed 35 mcg, and more preferably not to exceed 25 mcg, and even more preferably not to exceed 20 mcg, and most preferably 15 mcg or less, with EE and 17-Beta estradiol being preferred estrogens. A weaker estrogen or an estrogen having antiestrogenic activity (such as SERMS discussed below) can be used or added as a second estrogen to any of the regimens of this paragraph. One version of the regimen of this paragraph has the total dosage of norgestimate in a cycle not to exceed 8 mg. Another version of the regimen of this paragraph has the total dosage of norgestimate in a cycle exceeding 10 mg, preferably exceeding 15 mg. The cycle for the regimen is preferably 28 days, but other lengths are contemplated. The regimen of this paragraph can be bi-phasic, or can have at least three phases, and includes triphasic regimens. This invention provides a method of contraception which comprises administering to a female of child bearing age the OCP regimen of this paragraph. Alternatively, this invention contemplates a HRT regimen for post-menopausal women, and a HRT regimen for peri-menopausal women, having the ingredients and dosages mentioned above in this paragraph, except the estrogen dosages are 5 mcg or less EE dosage equivalent." (see Applicant's disclosure at the paragraph bridging pages 35-36)

The above disclosure, however, does not provide adequate support for claiming:

(a) a daily dosage of norgestimate in the range of 0.5-0.8 mg (see present claim 2);

(b) a daily dosage of norgestimate in the range of 0.8-1.2 mg (see present claim 4);

(c) a daily dosage of norgestimate in the range of at least 1.0 mg (see present claim 5);

(d) a daily dosage of norgestimate in the range of 1.0-1.8 mg (see present claim 6);

(e) multi-phasic administration, with one phase having a daily dosage of norgestimate of less than 0.25 mg (see present claims 15-16); or

(f) a regimen consisting of 21-28 daily dosages for a cycle (see present claims 17-19).

The ranges originally disclosed in the specification were unlimited ranges. Since the ranges as presently claimed after Applicant's amendments are now limited (i.e., an upper and lower limit is provided), such is properly considered to be a concept not sufficiently supported by the original disclosure.

Written Description

An Applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formula that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

The Examiner is guided in her opinion that Applicant has not adequately described the presently claimed subject matter by the MPEP at §2163-2163.05. In particular, while Applicant's specification as originally filed contained a disclosure of a dosage range of, for example, at least 0.5 mg **or** at least 0.8 mg of norgestimate, such does not entitle Applicant to now claim a dosage of norgestimate between 0.5-0.8 mg, because such represents a range that was not previously set forth or that would have been immediately envisaged by one skilled in the art from the specification as originally filed. "A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39USPQ2d 1895, 1905 (Fed. Cir. 1996)" (emphasis added), see MPEP §2163(I)(A). Also "See also *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) ('Whatever may be the viability of an inductive-deductive approach to arriving at a claimed subgenus, it cannot be said that such a subgenus is necessarily described by a genus

encompassing it and a species upon which it reads.' (emphasis added))."; see MPEP §2163.05(II).

Considering the teachings provided in the specification as originally filed, the Examiner finds that Applicant has failed to provide the necessary teachings, by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formula that fully set forth the claimed invention, in such a way as to reasonably convey to one skilled in the relevant art that Applicant had possession of the concepts of claims 2, 4-6 and 15-19 as enumerated above as points (a)-(f).

Accordingly, claims 2, 4-6 and 15-19 are deemed properly rejected.

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elliesen et al. (WO 97/11680; 1997), already of record, for the reasons of record as set forth at pages 4-6 of the previous Office Action dated April 1, 2005.

Newly added claims 2-19 are properly included in the present rejection because it would have been obvious from the teachings of Elliesen al. that the dosage amount and regimen would vary by patient, depending on such factors as, for example, age, weight and variations in body

weight and fat mass proportion, sex, severity of disease, toxicological consideration and the ability to tolerate such a compound and the resorption rate of the active agent(s) depending on the mode of administration, and determination of such would have been a matter well within the purview of the skilled artisan.

Applicant's amendments and accompanying remarks at page 1 of the Amendment filed September 6, 2005 each have been carefully considered, but fail to be persuasive in establishing error in the propriety of the present rejection.

Applicant states that Elliesen et al. teaches a specific EE dosage of 5-15 mcg and the use of the lowest possible estrogen dosage for the hormone replacement therapy product disclosed in the reference. Applicant relies upon page 5 of Elliesen et al. in support of this position and further asserts that Elliesen et al. fails to provide motivation to go any higher than 15 mcg of EE and, thus, teaches away from higher dosages.

Applicant's remarks are not found to be persuasive in establishing patentable distinction over the cited reference. It is noted that while Elliesen et al. expressly states ethinyl estradiol at a dosage range of 5-15 mcg, such is merely an exemplary dosage range and does not serve to limit the disclosure of the reference strictly to pharmaceutical compositions of a hormonal regimen wherein ethinyl estradiol is limited to a dose of 5-15 mcg. Applicant's attention is directed to Elliesen et al. at the paragraph bridging pages 14-15, which states:

"Examples of estrogens which can be employed in this invention (dosages shown are oral; transdermal dosages will vary therefrom in accordance with the absorption efficacy of the vehicle employed) are ethinyl estradiol and mestranol (5-15 mcg/day)...".

Applicant is reminded that the broad disclosure of Elliesen et al. teaches an estrogen component (i.e., ethinyl estradiol) in combination with a progestogen component (i.e., norgestimate) in a pharmaceutical preparation for administration as a hormonal regimen. The mere fact that Elliesen et al. has exemplified one dosage range of the estrogen component does not restrict the teachings of the reference only to dosage amounts given within such a range.

Applicant is reminded that, "A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including non-preferred embodiments...**Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or non-preferred embodiments**." (emphasis added; see MPEP §2123) Thus, although Rubin discloses one exemplary dosage range, such does not teach away from the broader disclosure of the reference, namely the pharmaceutical preparation containing ethinyl estradiol and norgestimate as a hormonal regimen.

Furthermore, Applicant asserts that "...higher dosages are not appropriate for the hormone replacement therapy product disclosed by Elliesen", but fails to point to a particular location in the reference that states, or reasonably suggests, that a "higher dosage" was not within the scope of the disclosed invention. Lacking any express statement or suggestion by the reference stating that "higher dosages" were excluded from the teachings of Elliesen et al., such an assertion merely reflects Applicant's personal interpretation of the reference and fails to be persuasive in establishing patentable distinction of the presently claimed subject matter.

In further response to the assertion that Elliesen provides no motivation to go any higher than 15 mcg of ethinyl estradiol, Applicant's attention is again directed to the previous Office Action of April 1, 2005 at page 5, which quotes Elliesen et al at page 2, paragraph 4: "a fixed

combination of an estrogen dosage and a progestogen dosage that is suitable for all menopausal women is impossible to design...one reason is the wide variation from individual to individual in the resorption rate which exists with all modes of administration except intravenous, which is not practiced in HRT...another reason why a fixed combination is not suitable is because of variations in body weight and fat mass proportion...A third reason is the interaction between estrogens and progestogens, i.e., progestogens may only become effective in the presence of estrogens because they stimulate the production of progestogen receptors." Such a teaching is considered express motivation to alter the dosage amounts of the hormone components of the active preparation, since Elliesen et al. acknowledges that the variation in the estrogen and progestogen dosage amounts necessary to effect therapeutic benefit will vary from person to person and, thus, will require modifications to tailor the regimen to the hormonal needs of each individual.

In further response thereto, Applicant's attention is drawn to MPEP at §2144.05, which states, "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages...Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." Although the present claims are drawn to mg dosage amounts of the active agents, such a motivation is considered, nonetheless, relevant.

For these reasons and those already made of record at pages 4-6 of the previous Office Action dated April 1, 2005, rejection of claims 1-19 remains proper and is **maintained**.

Double Patenting

Obviousness-Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21, 34, 37 and 44 of copending U.S. Patent Application No. 09/754,732, for the reasons made of record at pages 6-8 of the previous Office Action dated April 1, 2005.

Newly added claims 2-19 are properly included in the present rejection because it would have been *prima facie* obvious to one of ordinary skill in the art that the dosage amount and regimen of the active agent(s) would vary by patient, depending on such factors as, for example, age, weight and variations in body weight and fat mass proportion, sex, severity of disease, toxicological consideration and the ability to tolerate such a compound and the resorption rate of

the active agent(s) depending on the mode of administration, and determination of such would have been a matter well within the purview of the skilled artisan.

Applicant's amendments and remarks at page 1 of the Amendment filed September 6, 2005 each have been carefully considered, but fail to be persuasive in establishing error in the propriety of the present rejection.

Applicant submits that nothing in that disclosure [Elliesen et al.] would render obvious the specific products now recited in claim 1, or the products of the new claims.

In light of the reasons already made of record at page 6-8 of the previous Office Action, the present claims remain properly rejected as being obvious variants of claims 21, 34, 37 and 44 of the copending application.

Moreover, Applicant's remarks regarding the present rejection under the judicially created doctrine of obviousness-type double patenting amount to nothing more than a general allegation that the claims define a unobvious patentable invention over the copending claims without specifically pointing out how the language of the newly amended and newly added claims patentably distinguishes them from those of the copending application.

For these reasons and those already made of record at pages 6-8 of the previous Office Action dated April 1, 2005, rejection of claims 1-19 remains proper and is **maintained**.

Conclusion

Rejection of claims 1-19 is deemed proper and is **maintained**.

No claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (8:30 AM-6:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leslie A. Royds
Patent Examiner
Art Unit 1614

December 12, 2005

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